Examiner's Amendment and Comments

1. Request for continued examination (i.e., RCE) under 37 C.F.R. §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 04 February 2008 after a Final action mailed 02 January 2008. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 02 January 2008 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission and the RCE filed 04 February 2008 have been entered. Accordingly an RCE has been established and the action on RCE follows.

2. The responsive amendment filed 08 04 February 2008 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Withdrawals of Rejection based on Applicant's Amendments and Remarks

3. In view of remarks and amendments filed 04 February 2008 the following objections and rejections in the Office Action mailed 02 January 2008 are hereby withdrawn:

- Objection to Claim 32 under 35 U.S.C. §132(a) because it introduces new matter into the disclosure;
- Rejection of Claim 32 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement;
- Indefiniteness rejection of Claim 34 under 35 U.S.C. §112, second paragraph; and
- Anticipatory/obviousness rejections of Claims 6-7, 10-13 and 32-34 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Roth et al (U.S. Patent 5,545,535) with evidence provided by Mansour (U.S. Patent 4,665,024).

Claims Status

4. Claims 1-5, 8-9 and 14-31 have been cancelled.

5. Claims 6-7 have currently been amended.

6. Claims 6-7, 10-13 and 32-34 are pending and are examined on Merits.

Examiner's Amendment

7. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on XX April 2008 with Mr. Gregory Zayia, Applicants' Representative.

In the Title:

Please change the current title with, Bacteria Counting Method

In the Claims:

The following listing of claims will replace all prior versions, and listings, of claims in the instant application:

Listing of Claims:

1-5. (Canceled)

6. (Currently amended) A method for counting bacteria in a clinical specimen that comprises Gram positive and Gram negative bacteria, the method comprising:

preparing a first assay sample by dividing the clinical specimen into at least two parts and staining a first specimen part using a fluorescent dye, thereby producing a difference in fluorescent intensity between live bacteria and dead bacteria;

preparing a second assay sample by staining all bacteria in a second specimen part using said fluorescent dye and a surface-active agent;

detecting a first optical information from the first assay sample;

detecting a second optical information from the second assay sample;

classifying and counting dead bacteria in the first assay sample based on the first optical information;

classifying and counting [[all]] total bacteria in the second assay sample based on the second optical information; and

calculating [[a]] the number of live bacteria based on a total bacteria count obtained from the second assay sample and [[a]] the dead bacteria count obtained from the first assay sample.

7. (Previously Presented) The method of Claim 6, wherein-the said fluorescent dye comprises a polymethine dye.

8-9. (Canceled)

10. (Original) The method of Claim 6, wherein the surface-active agent comprises a cationic surface-active agent.

11. (Original) The method of Claim 6, wherein the staining is performed at a pH of between about 2.5 and about 4.5.

12. (Original) The method of Claim 6, wherein the first optical information and the second optical information comprise fluorescent light.

13. (Previously Presented) The method of Claim 6, wherein the first optical information comprises fluorescent light and scattered light, and wherein the second optical information comprises fluorescent light and scattered light.

14-31. (Canceled)

32. (Previously Presented) The method of claim 6, wherein the preparing of the second assay sample comprises damaging a cell membrane of the bacteria with the surface active agent to stain dead and live bacteria with said fluorescent dye.

33. (Previously Presented) The method of claim 6, wherein the first optical information and the second optical information are detected by using a flow cytometer.

34. (Previously Presented) The method of claim 6, wherein the dead bacteria are stained more strongly than the live bacteria in the preparing of the first assay sample.

Examiner's Reasons for Allowance

8. The closest art are:

- U.S. Patent 4,665,024 issued 12 May 1987 to Mansour. Mansour teaches plurality of fluorescent dyes to enhance performance of Gram stain to distinguish between Gram positive and Gram negative bacteria, but not between live and dead bacteria as is claimed in the instant application;

- U.S. Patent 5,545,535 A issued 13 August 1996 to Roth et al. Roth et al teach 4 different dyes to stain bacteria, each differing from the other for its affinity for the Gram positive or Gram negative, dead or alive bacteria. For example, dye II stains all dead bacteria and only the Gram positive, whereas, dye of formula I is a highly cell membrane permeant cyanine dye and labels all bacteria, live or dead. None of the 4 dyes in Roth et al., teach a dye that simultaneously distinguishes a dead, a live and a Gram negative, or Gram positive bacteria, which is the inventive concept claimed in the instantly presented Claims;

- U.S. Patent 7,309, 581 B2 issued 18 December 2007 to Sakai Yasuhiro et al. Sakai et al. discuss polymethine fluorescent dyes to stain Gram negative and Gram positive bacteria but do not distinguish between dead or live bacteria using the same single dye; and

- US PreGrant Publication 2004/0175781 A1 to Sakai Yasuhiro published 09 September 2004. Sakai et al teach a bacterial stain and diluent along with a method to stain bacteria with a polymethine dye on a sample in the presence of a substance capable of reducing nitrite ions to stain bacteria in the sample and subsequently examine the stained preparation in a flow-cytometer. They, however, do not teach a method wherein one single polymethine dye distinguishes between the dead and live as well as Gram Negative and Gram positive bacteria in a clinical sample or a sample believed to have a mixed population comprised of dead and live or viable and non- viable Gram positive or Gram negative bacteria..

Thus, none of the cited references either separately or in combination teach a method to stain and detect Gram positive and Gram negative dead or alive bacteria wherein the bacterial population is stained with one single dye, wherein said dye is a polymethine dye..

9. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. Claims 6-7, 10-13 and 32-34 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

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25 April 2008

/Jon P Weber/
Supervisory Patent Examiner, Art Unit 1657